

**Notice of Allowability**

Application No.

10/621,027

Examiner

Eric S. Olson

Applicant(s)

CHEUNG, NAI-KONG V.

Art Unit

1623

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment submitted November 6, 2007.
2. ☒ The allowed claim(s) is/are 193-207, 212, 219-227 and 232.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>10/26/07, 12/17/07</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                             | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

### Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

### Abstract

The abstract is amended as follows:

This invention provides a composition comprising an effective amount of (1-3)- $\beta$ -glucan derived from barley capable of enhancing efficacy of antibodies. This invention further provides the above compositions and a pharmaceutically acceptable carrier. This invention also provides a method for treating a subject with cancer comprising administering the above-described composition to the subject. ~~This invention provides a composition comprising effective amount of glucan capable of enhancing efficacy of vaccines. This invention also provides a method of treating a subject comprising administering the above pharmaceutical composition to the subject. This invention provides a composition comprising effective amount of glucan capable of enhancing efficacy of natural antibodies. This invention provides a composition comprising effective amount of glucan capable of enhancing host immunity. This invention also provides a composition comprising effective amount of glucan capable of enhancing the action of an agent in preventing tissue rejection.~~

### **Detailed Action**

This office action is a response to applicant's communication submitted November 6, 2007 wherein claims 193-207, 212, 219-227, and 232 are amended and claims 208-211, 213-218, 228-231, and 233-238 are cancelled. This application is a continuation in part of international application PCT/US02/01276, filed January 15, 2002, which claims benefit of provisional application 60/261911, filed January 16, 2001.

Claims 193-207, 212, 219-227, and 232 are pending in this application.

Claims 193-207, 212, 219-227, and 232 as amended are examined on the merits herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2007 has been entered.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claims 193-198, 208-224, and 228-238 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does not teach a

composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claims 200, 201, 207, 226, and 227 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al. further in view of Cheever et al., Onizuka et al., Herrera et al., or Rai et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does not teach a composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claims 216-218 and 236-238 under 35 USC 112, second paragraph, as being indefinite for reciting viscosities of the claimed glucans without disclosing the conditions under which the specific viscosity is to be obtained, has been fully considered and found to be persuasive to remove the rejection as the rejected claims are cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claims 216-218 and 236-238 under 35 USC 112, first paragraph, for introducing new matter into the claims by reciting glucans having viscosities that are not supported by the specification as originally filed, has been fully considered and found to

be persuasive to remove the rejection as the rejected claims are cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claims 200, 202, 203, and 226 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al. further in view of Maloney et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does not teach a composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claim 205 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al. further in view of Bergman et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does not teach a composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claim 202 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al. further in view of Capurro et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does not teach a

composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claims 199, 206, and 225 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al. further in view of Soiffer et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does not teach a composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claim 197 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al. further in view of Ren et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does not teach a composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claim 204 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al. further in view of Ren et al. in view of D'Amico et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does

not teach a composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 5, 2007, with respect to the rejection of instant claims 197 and 204 under 35 USC 103(a) as being unpatentable over Yan et al. in view of Jamas et al. further in view of Mendelsohn et al., has been fully considered and found to be persuasive to remove the rejection as the prior art does not teach a composition in which the beta-glucan is a barley beta-glucan. Therefore the rejection is withdrawn.

**Allowable Subject matter**

Claims 193-207, 212, 219-227, and 232 are seen to be allowable. The claimed combination of an anti-tumor antibody and a (1,3)-beta-glucan from barley is not seen to be taught or fairly suggested by the prior art, as discussed below.

These claims are drawn to material adequately described and enabled by Applicant's specification. For example, written description under 35 USC 112 is provided by the summary of the invention on pp. 4-5 of the specification as originally filed. The three series of experiments disclosed on pp. 23-92 of the specification provide adequate information to enable one skilled in the art to make and use the invention.

Furthermore the claimed invention is not seen to be taught or fairly suggested by the prior art. Although Yan et al. does already disclose the combined administration of

antibodies and beta-glucan, which could be orally administered by one of ordinary skilled in the art as disclosed by Jamas et al., the beta-glucan used by Yan et al. is a yeast beta-glucan having significantly different properties from the claimed barley beta-glucan. For example, the yeast glucan has a much smaller molecular weight, is soluble, has only (1,3) backbone linkages, and is branched with (1,6) side chains. Therefore there would be no reason for one of ordinary skill in the art to substitute the barley beta-glucan for the yeast beta-glucan and use this glucan in combination with any prior art anti-tumor antibodies. Furthermore, it is unexpected based on the prior art that this barley beta-glucan would specifically enhance the efficacy of antitumor antibodies, as opposed to merely producing an additive antitumor effect.

For these reasons, the subject matter of claims 193-207, 212, 219-227, and 232 is seen to be allowable.

Accordingly, Applicant's amendment submitted November 6, 2007, and the accompanying examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably



accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number:  
10/621,027  
Art Unit: 1623

Page 10

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